MEDICAL COLLEGE OF WISCONSIN CANCER CENTER **Cancer Center Clinical Trials Office**

STANDARD OPERATING PROCEDURE INTERNAL QUALITY ASSURANCE REVIEWS	
SOP#: 6.5.2	**Original Approval Date: 7/11/18**
Version#: 2.0	**Revision Dates: 3/16/20**

1.0 PURPOSE/BACKGROUND

This SOP describes the plan for Internal Quality Assurance Reviews (IQARs) in the Medical College of Wisconsin Cancer Center Clinical Trials Office (CCCTO) by the Quality Assurance (QA) staff. An important element of a quality program for research is proper oversight. IQARs evaluate the research studies to ensure that research conducted at the Medical College of Wisconsin (MCW) Cancer Center is of the highest quality and meets MCW and regulatory agency standards. The goals of IQARs are to identify areas of noncompliance or potential noncompliance and to provide education and suggestions for corrective action. Investigators should view the role of the IQAR as performing an essential function in maintaining a high state of research compliance.

2.0 SCOPE

This SOP applies to all IQARs conducted by the MCW CCCTO internal QA staff. This SOP applies to all personnel involved in the implementation and coordination of clinical trials involving human subjects in all disease teams within CCCTO.

3.0 RESPONSIBILITY

Individuals impacted by the new or updated SOP(s) may include:

- Study staff
- Education/QA staff
- Multi-site staff
- Investigational Drug Pharmacy
- MCW Cancer Center Scientific Review Committee (SRC)
- MCW Cancer Center Data & Safety Monitoring Committee (DSMC)
- Other applicable staff involved in the conduct of the study

4.0 DEFINITIONS

Refer to Glossary of Common Terms and Definitions.

Internal Quality Assurance Review (IQAR): A formal review of study records by the MCW CCCTO Quality Assurance staff to ensure the accuracy of the study data, to evaluate reasonable adherence to a protocol and MCW Approved SOPs and guidelines, and to verify the protection of human subjects.

5.0 ROLES AND PROCEDURES

Risk Level Assignment

5.1 Prior to study start up, all new Investigator Initiated Trials (IITs) will be reviewed and assigned a risk level by the Cancer Center Scientific Review Committee and confirmed by the Cancer Center Data Safety Monitoring Committee (DSMC). QA oversight will be based on the risk level of the study. The QA team will use Cancer Center Data Safety Monitoring Plan as a framework for reviews. Any aspect of the review may change at the discretion of the QA team due to factors such as time and resource constraints. Changes will be documented accordingly.

Selection of Trials

5.3. Trials will be selected for directed IQARs or routine IQARs. Directed IQARs (i.e., "for cause") may be initiated per the request of the DSMC, IRB, Research Manager, Physician Investigator, or Administrative personnel. Directed IQARs may include a review of trials being coordinated by new CCCTO employees. Routine IQARs will focus primarily on IITs. Subjects will be selected randomly. In the case of a multi-site trial, subjects may be selected from any participating institution. Routine IQARs may be done to satisfy protocol-specified monitoring requirements for IITs. If the DSMC defers review of a study, routine IQARs will also be deferred. If a trial has been reviewed recently by the MCW's OHRP office, it may be deferred for a routine IQAR.

5.4 During the IQAR, the QA staff may inspect all or a percentage of study records (e.g., completed CRFs, source documents, regulatory files, drug accountability records, medical records, OnCore, etc.). This will be at the discretion of the QA staff.

Scheduling & Notification

5.5 The QA staff will notify the following study staff of the upcoming IQAR at least 10 business days prior to the proposed IQAR date: Research Manager, Study Coordinator, Regulatory Manager, Regulatory Coordinator/Specialist, and Principal Investigator. This may be rescheduled to a later date at the discretion of the QA staff for considerable conflicts.

5.6 The QA staff will conduct the IQAR in a timeframe considered sufficient to review appropriate study material, as determined by the QA staff. Logistics of review will be arranged between QA staff and Study Coordinator.

IQAR Summary Meeting

5.7 Summary Meetings will be conducted as needed at an agreed upon time among attendees. The following staff may be invited to the Summary Meeting at the discretion of the QA staff: Principal Investigator, applicable sub-investigators, CCCTO Administrative Director, Research Manager, Regulatory staff, applicable study coordinators, and investigational pharmacy.

5.8 In the Summary Meeting, the QA staff will review the draft report from the IQAR and preliminary findings. The QA staff may also make recommendations for quality improvement, suggested protocol revisions, and education.

5.9 Following the Summary Meeting, the study staff will have approximately 3 business days to confirm that the draft report is accurate to the best of their knowledge.

Follow-up

5.10 A written final report will be provided to the study team and Faculty Committee Coordinator after completion of the IQAR. All findings, recommendations, and action items will be detailed in the final report.

5.11 A written response to the final report should be provided to the QA staff within 30 days of receipt of the final report. The study staff may request an extension for considerable conflicts.

5.12 A copy of the report and the responses will be filed with the CCCTO QA staff and uploaded to Oncore. A copy of the report will be provided to the Cancer Center Data Safety Monitoring Committee.

5.13 A follow up IQAR or further external auditing may be recommended based on the IQAR findings (e.g., Clinical Translational Science Institute-CTSI, MCW Office of Research, etc.).

6.0 REFERENCES

Oversight of Clinical Investigation – A Risk-Based Approach to Monitoring, US Department of Health and Human Services, Food and Drug Administration, August 2013

7.0 APPENDICES

Appendix I: Definitions

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Revision dates:
7/11/18, v1.0
3/16/20, v2.0

Review dates:
7/11/18, 3/16/20